

REMARKS

Claim Amendments:

Claims 1-23 and 27-28 are withdrawn. Claims 24-26 remain in the application. Claim 24 has been amended to further describe the microparticles and the wall-forming materials. Support for the amendment to claim 24 can be found, for example, on page 8, lines 27-30 and page 32, lines 21-23 of the specification. Claim 25 has been amended herein to delete the term "acids." As will be discussed below, this amendment is made solely to expedite the prosecution of this application. Claim 26 has been amended to change the term "is" to "includes". Entry of the claim amendments is respectfully requested.

Interview Summary

Applicants thank the Examiner for granting a telephonic interview with the Applicants' representative, Mary Ann Dillahunty, on July 27, 2005. At the interview, the attendees discussed obtaining the technology center director's signature on the office action and restarting the period for reply. In addition, the Examiner requested that the Applicants submit copies of the NPL documents listed in the PTO-1449 form submitted on May 11, 2004.

Information Disclosure Statements:

The Examiner noted that the Information Disclosure Statement filed May 11, 2004, fails to comply with 37 C.F.R. § 1.98(a)(2), for not submitting a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. A PTO 1449 form, which includes the references not considered by the Examiner as well as additional references, and an Information Disclosure Statement accompany this response. Applicants respectfully request that the Examiner consider these documents and initial the PTO 1449 accordingly.

Rejection Under 35 U.S.C. § 112:

Applicants believe that the Examiner intended to reject claim 25 under 35 U.S.C. § 112, and not claim 26, as stated on page 3 of the Office Action. The Examiner's rejection of claim 25 under 35 U.S.C. § 112, first paragraph as lacking written description is respectfully traversed. Applicants submit that the disclosure of acids as optional components at page 32, lines 25-30 of the specification is clear support for their use in the claimed methods. Accordingly, there is sufficient written description support for this claim. However, Applicants have amended claim 25 to delete the term "acids." This amendment is made solely to expedite the prosecution of this application and not for reasons related to patentability.

Withdrawal of the written description rejection is requested.

Rejections Under 35 U.S.C. § 102:

1. U.S. Patent No. 4,180,593

The Examiner's rejection of claims 24-25 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,180,593 (the '593 patent) to Cohan et al. is respectfully traversed.

The '593 patent does not teach a method for preparing microparticles, as required by claims 24 and 25. The '593 patent discloses methods of making blown beads which comprise an edible film forming food material (e.g., col. 2, lines 14-18). The methods disclosed in the '593 patent include subjecting the beads to both a heated zone and a quench cooling zone (e.g., col. 1, lines 56-61). The '593 patent teaches that the advantage of using the quench cooling zone is that the beads are "much harder and thereby resist crushing during shipment" (e.g., col. 5, lines 1-6). However, the '593 patent does not address forming microparticles with a specified wall thickness. Rather, the '593 patent describes improving wall strength and integrity by using quench cooling. The '593 patent does not require any particular wall thickness for the beads. Conversely, the claimed methods are drawn to preparing microparticles having a wall thickness of about 100 to 500 nanometers. Further, the '593 patent does not describe microparticles

containing a therapeutic bioactive agent, as required by claims 24 and 25. Thus, the '593 patent does not anticipate the presently claimed invention.

2. U.S. Patent No. 2,797,201

The Examiner's rejection of claims 24-25 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 2,797,201 (the '201 patent) to Veatch et al. is respectfully traversed.

The '201 patent does not teach a method for preparing microparticles, as required by claims 24 and 25. The '201 patent is directed to forming balloons from film forming materials (e.g., col. 3, lines 4-29). The balloons can have an average diameter between 1 to about 500 microns or larger, up to one-eighth of an inch (e.g., col. 4, lines 58-75). Beads formed with plastic skins have a diameter that is about 5 to 20 times the thickness of the plastic skin (e.g., col. 4, lines 58-75). Additionally, the use of therapeutic bioactive agents is not taught or suggested by the '201 patent. Accordingly, the '201 patent does not describe forming microparticles from wall-forming materials that include a therapeutic bioactive agent and have a wall thickness of about 100 to 500 nanometers. Thus, the '201 patent does not anticipate the presently claimed invention.

3. U.S. Patent No. 5,605,673

The Examiner's rejection of claim 24 under 35 U.S.C. § 102(a) and (e) as anticipated by U.S. Patent No. 5,605,673 (the '673 patent) to Schutt et al. is respectfully traversed.

The '673 patent does not teach a method for preparing microparticles, as required by claim 24. The '673 patent describes spray drying materials, such as materials that dissolve or hydrate in aqueous solution, to form hollow spheres (e.g., col. 19, lines 25-39). However, the '673 patent does not describe the thickness of the walls of the spheres as being between about 100 and 500 nanometers, as required by claim 24. Nor does the '673 patent teach or suggest that the hollow spheres contain a therapeutic bioactive agent. Thus, the '673 patent does not anticipate claim 24.

Withdrawal of the anticipation rejections is requested.

Rejection Under 35 U.S.C. § 103:

The Examiner's rejection of claim 26 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,605,673 (the '673 patent) to Schutt et al. is respectfully traversed.

As discussed above, the '673 patent fails to teach or suggest forming microparticles having a wall thickness of about 100 to 500 nanometers or including a therapeutic bioactive agent, as required by claim 26. Accordingly, even if one were to use albumin as the wall-forming material, the '673 patent does not teach or suggest all of the limitations required by claim 26. For at least these reasons, the Applicants submit that no *prima facie* case of obviousness has been made with respect to claim 26 after amendment of claim 24.

Withdrawal of the obviousness rejection is requested.

Double Patenting Rejections:

1. U.S. Patent No. 6,565,885

Claim 24-25 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of U.S. Patent No. 6,565,885. Applicants respectfully request that the Examiner hold this rejection in abeyance until the claims are determined otherwise to be allowable.

2. U.S. Patent No. 6,207,135

Claim 24 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the disclosure of U.S. Patent No. 6,207,135 (the '135 patent). Applicants submit that this is an improper double patenting rejection. No claim of this patent is mentioned in the office action. In an obviousness-type double patenting rejection, only the claims of the issued patent, not the entire specification, may be considered in determining the obviousness of the second set of claims. (See, e.g., MPEP 804(II)(B).)

Further, the Examiner has stated that the "[i]nstant application requires a wall forming material and a blowing agent without specificity in the method of making the microparticles." Claim 24 specifically requires spray-drying wall-forming material. The '135 patent includes claims directed to production of gaseous microparticles, including freeze drying a suspension mixed with a suitable pharmaceutically acceptable cyroprotector (e.g., claim 6). Thus, claim 24 in the instant application requires a different method of forming microparticles than the process claims of the '135 patent.

Withdrawal of the rejection is requested.

Conclusions:

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims of this application at an early date is earnestly solicited.

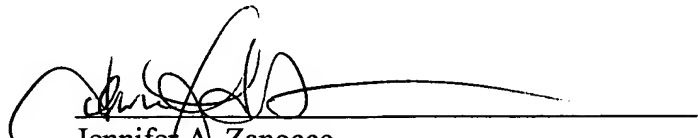
In the event that a telephone conversation may expedite the prosecution of this application, the Examiner is invited to call the undersigned at (650) 839-5138.

Please apply any required charges or credits to deposit account 06-1050.

Respectfully submitted,

Date:

November 9, 2005


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